

Maryland 2009 Influenza A (H1N1) Monovalent Vaccine Provider Agreement and Initial Order Form

Your participation in the 2009 Influenza A(H1N1) monovalent vaccine vaccination effort is greatly appreciated as a vital service that will protect individuals and the public against 2009 H1N1 influenza. The 2009 Influenza A(H1N1) monovalent vaccine has been purchased by the federal government as a means of protecting the public against 2009 H1N1 influenza. It is being made available to immunization providers working in partnership with state and local public health departments to vaccinate individuals for whom the vaccine is recommended. This Provider Agreement specifies the conditions of participation in the 2009 Influenza A(H1N1) monovalent vaccine vaccination effort in the U.S. and must be signed and submitted to the immunization program prior to receipt of the vaccine.

The immunization provider agrees to:

1. Administer the 2009 Influenza A(H1N1) monovalent vaccine according to the recommendations of CDC's Advisory Committee on Immunization Practices as adopted by the Centers for Disease Control and Prevention.
2. Store and handle the vaccine in accordance with the package insert provided with the vaccine including in compliance with cold chain requirements.
3. Provide a current Vaccine Information Statement to each individual before vaccination, and answer questions about the benefits and risks of vaccination, including different indications for live versus inactivated vaccines.
4. Record in the patient's medical record or in an office log the date of administration, the site of administration, the vaccine type and lot number, and the name of the immunization provider for each individual vaccinated. The record must be kept for a minimum of three years following vaccination.
5. Report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (1-800-822-7967, <http://vaers.hhs.gov/contact.htm>).

In addition, the provider:

6. Can not charge patients, health insurance plans, or other third party payers for the vaccine, the syringes or the needles as these are provided at no cost to the provider. The provider/facility is also prohibited from selling H1N1 vaccine, syringes or needles.

7. May charge a fee for the *administration* of the vaccine to the patient, their health insurance plan, or other third party payer. The administration fee cannot exceed the regional Medicare vaccine administration fee. If the administration fee is billed to Medicaid, the amount billed cannot exceed the state Medicaid administration fee.
8. May either administer the 2009 Influenza A (H1N1) monovalent vaccine for free to individuals who cannot afford the administration fee, or refer these individuals to a public health department clinic or affiliated public health provider for vaccination.
9. Must report the number of doses of 2009 Influenza A (H1N1) monovalent vaccine administered to individuals as requested by the state or local public health department.
10. Must report to the state health department the number of doses of vaccine that were not able to be used because the vaccine expiration date was exceeded or the vaccine was wasted for other reasons. These doses must be disposed of in accordance with state regulations for biological waste.
11. Are strongly encouraged to provide an immunization record card to the vaccine recipient or parent/guardian to provide a record of vaccination, to serve as an information source if a Vaccine Adverse Event Reporting System report is needed, and to serve as a reminder of the need for a second dose of vaccine (if necessary). Immunization cards will be included in each shipment of vaccine.
12. Vaccine shipped at the Provider's request under this agreement to receiving location outside the state (e.g., a distributor for a pharmacy chain) must be offered for administration at facilities located in the State of Maryland.
13. The person signing this agreement on behalf of the facility or organization will assure that providers participating in the H1N1 vaccination program at this facility are made aware of their obligations under the terms of this agreement. The Maryland Department of Health and Mental Hygiene's obligations and duties are limited to the coordination efforts previously stated.
14. Providers are strongly encouraged to check and document vaccine storage temperatures at least twice daily when the facility is open to assure that vaccine is stored at proper temperatures (2°-8° Celsius, or 35°-46° Fahrenheit).
15. In the event of a vaccine storage failure, the provider agrees to notify the Department of Health and Mental Hygiene by email at H1N1Info@DHMH.state.md.us. The provider agrees not to administer vaccine involved in a storage failure unless the vaccine manufacturer indicates that its use is acceptable.

16. Providers will submit to DHMH on at least a weekly basis the following data elements on all 2009 Influenza A (H1N1) Vaccine Administration.

Note: Data may be submitted using the DHMH administration tracking form or ImmuNet. Existing users of ImmuNet are expected to use ImmuNet for submission of data to DHMH. All other providers will be supplied triplicate forms for capturing the above data elements and which may also serve as a patient record. (Large health care organizations who have a well-functioning electronic record systems capable of extracting, formatting and periodically transmitting a single file with the required patient-specific data elements may wish to inquire about electronic reporting of H1N1 vaccine administration data. Inquiries about such may be made by emailing H1N1INFO@dhmh.state.md.us).

Required data elements:

Patient
Last Name
First Name
Zip Code
DOB
Gender
Vaccine dose number
Date vaccine was administered
Provider PIN number

Requested but not required data elements:

Patient Jurisdiction (county/city code)
Patient's telephone number
Ethnicity
Race
Target Group
Pregnancy
Live with/care for children less than six months old
Direct patient contact
Underlying risk factor/chronic condition
Vaccine Information
Vaccine manufacturer name
Lot number

17. The providers acknowledge that the information pertaining to the provider's name and address, as well as the number of doses delivered under this agreement may be made to the public.

If the information is publicly made available, how would you like information about your vaccination site to be listed? Please choose one below:

- Open for H1N1 vaccination of new patients/general public
- Vaccine available to current patients only; not open to new patients/general public
- Other_____

18. The provider acknowledges that receipt of H1N1 vaccine shall constitute acceptance of the terms of this agreement.

H1N1 Initial Vaccine Order Form

Before placing your order, it is important to assess your refrigerator storage capacity and realistic expectations for use. Boxes of supplies to administer the selected vaccine will arrive the day before or the day of the shipment (supplies may include, as needed: patient immunization cards, syringes, needles, alcohol swabs, sharps containers).

This initial order **MUST NOT EXCEED** your storage refrigerator's capacity. Boxes of vaccine may arrive at once or in multiple shipments as product is released.

Your initial order should reflect the amount of vaccine you anticipate being able to administer in a 30 day period.

The following questions will appear on the online order form; please take time to develop the most accurate response for your facility/site.

1. Please provide the date you are submitting your order:
2. Please provide information so that we may contact you directly should there be questions about your order:
3. Please provide the Provider identification Number (PIN). Please enter only one PIN number.
4. Please provide your facility's office hours and days of operation:
5. Please indicate any specific shipping instructions for your facility (e.g. days vaccine cannot be received, etc.).
6. How many doses (in increments of 10) of injectable vaccine would you like to order? Please select vaccine by formulation appropriate for the age group of the intended recipients.

Pre-filled syringes Preservative-free, 0.25ml (6-35 months of age) _____

Pre-filled syringes Preservative-free, 0.5ml (4+ years of age)_____

Multi-dose vials (6 months and older) (order in doses) _____

7. How many doses (in increments of 10) of nasal spray Live Attenuated Influenza Vaccine (LAIV) (2-49 years of age, healthy, not pregnant) would you like to order?

SAMPLE